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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,623	09/12/2001	Ryan McGuinness	41618	6108
22462	7590	03/22/2004	EXAMINER	
GATES & COOPER LLP HOWARD HUGHES CENTER 6701 CENTER DRIVE WEST, SUITE 1050 LOS ANGELES, CA 90045			WINKLER, ULRKE	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831,623	Applicant(s) MCGUINNESS ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed December 31, 2003 in response to the Office Action of October 1, 2003 is acknowledged and has been entered. Claims 3-6 have been added. Claims 1-6 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection of claims 1 and 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment.

The rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicant's amendment.

The rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

The rejection of claims 1, and newly added claims 3 and 5 under 35 U.S.C. 102(a) or 102(e) as being anticipated by Carrano et al. (U.S. Pat. No. 5,739,118; see IDS) **is maintained** for reasons of record.

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Applicant's have amended the claims to include the limitation that the "wherein the splice acceptor site is less efficient than the splice donor site". Applicant's arguments have been fully considered but fail to persuade. According to the specification a construct that comprises the 5' major splice donor site and the splice acceptor site of the third exon of the HIV tat and rev genes (see page 3, line10-17) would meet the requirement of "wherein the splice acceptor site is less efficient than the splice donor site". The instant invention is drawn to a nucleic acid construct comprising in order a promoter, a splice donor site, a gag/pol coding region, a RRE element a splice acceptor site and a selectable marker.

Carrano et al. disclose a nucleic acid construct (see figure 4 and 5, and example 36) that comprises gag/pol and RRE with a splice acceptor site. The construct is inserted into a plasmid selected from A-D (see figure 4), and the plasmid contains a selectable marker. The reference also indicates that in some embodiments there is a splice donor upstream of the gag transnational start codon (see column 22, lines 25-30), this would be the 5' major splice donor site. The constructs also comprise the regulatory genes tat and rev. The insert has been cloned in such a way to conserve the HIV splice acceptor site (see column 38, lines 40-44), which is the site after the third exon and thereby meets the limitation of being "less efficient". Therefore, the instant invention remains rejected over Carrano et al.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Yu et al. (Journal of Virology, 1996; see IDS) is **withdrawn**. Upon review and reconsideration of the prior rejection it is noted that the HIV-g pt construct has the sequences in the order starting with

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a promoter, a splice donor site, a gag/pol coding region, a selectable marker followed by the RRE element and the splice acceptor site.

The rejection of claims 1, 2 and newly added claims 3-6 under 35 U.S.C. 102(a) as being anticipated by Kaul et al. (Virology, September 1998) **is maintained** for reasons of record.

Applicant's have amended the claims to include the limitation that the "wherein the splice acceptor site is less efficient than the splice donor site". Applicant's arguments have been fully considered but fail to persuade. Applicant argues that the references fail to suggest selecting splice acceptor site that is suboptimal. According to the specification a construct that comprises the 5' major splice donor site and the splice acceptor site of the third exon of the HIV tat and rev genes (see page 3, line10-17) would meet the requirement of "wherein the splice acceptor site is less efficient than the splice donor site".

Kaul et al. disclose a nucleic acid construct (see figure 1, pHVP) that comprises gag/pol and RRE, specifically pHVP and pHIV-GIP. In a cell that is able to propagate the retroviral vector and produce particles, gag/pol and env constructs are present as well (see page 173, column1, 1st paragraph). In this instance the HVP or pHIV-GIP is the first construct and the pTIRvENV is the second expression construct. The splice acceptor sites of tat and rev meet the requirement of being suboptimal, the pHVP construct comprises the splice acceptor site of rev and tat. Therefore, the instant invention remains rejected by Kaul et al.

New rejection in view of Applicant's amendment:

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Claim 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the splice acceptor sites of tat and rev genes, does not reasonably provide enablement for “wherein the splice acceptor site is less efficient than the splice donor site”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification has not disclosed a means of ascertaining when a splice acceptor site would be deemed to be less efficient/suboptimal. There is no guidance in the specification to teach where the sequence should be substituted, and therefore, the functionality of the splice acceptor site is unpredictable. Moreover, one of skill in the art would not know which position of the substitution would retain the characteristics of maintaining the function of being a splice acceptor without undergoing extensive experimentation. The specification is enabled for the combination of using the HIV 5’ splice donor site and the splice acceptor site of the third exon of HIV rev and tat genes. The instant specification does not provide enablement commensurate with the full scope of the claims.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “less efficient” is indefinite, because the ordinary artisan would not know the metes and bounds of what is contemplated by the term. More importantly the ordinary artisan would not know when looking at a sequence what sequences will fall within the scope of the claim.

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Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

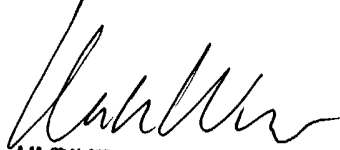
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER

3/19/12